

Application Serial No. 07/402,450
Amendment After Final dated 18 September 2006
Reply to Office Action mailed 16 March 2006

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claims 1-113 (canceled).

Claim 114 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;
- (ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence consists of the selected target viral RNA sequence with a multibase insert into a site within the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;
- (iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;
- (iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and
- (v) determining the amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

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Claim 115 (previously presented): The process of claim 114, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 116 (previously presented): The process of claim 114, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 117 (previously presented): The process of claim 114, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 118 (previously presented): The process of claim 117, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 119 (previously presented): The process of claim 118, wherein the label is an isotope or a fluorophore.

Claim 120 (previously presented): The process of claim 117, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 121 (previously presented): The process of claim 120, wherein the label is an isotope or a fluorophore.

Claim 122 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;

(ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence consists of the selected target viral RNA sequence with a multibase insert into a site within the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;

(iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;

(iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and

(v) determining the amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 123 (previously presented): The process of claim 122, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 124 (previously presented): The process of claim 122, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 125 (previously presented): The process of claim 122, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 126 (previously presented): The process of claim 125, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 127 (previously presented): The process of claim 126, wherein the label is an isotope or a fluorophore.

Claim 128 (previously presented): The process of claim 125, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 129 (previously presented): The process of claim 128, wherein the label is an isotope or a fluorophore.

Claim 130 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase insert into a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 131 (previously presented): The process of claim 130, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 132 (previously presented): The process of claim 130, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 133 (previously presented): The process of claim 130, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 134 (previously presented): The process of claim 133, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 135 (previously presented): The process of claim 134, wherein the label is an isotope or a fluorophore.

Claim 136 (previously presented): The process of claim 133, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 137 (previously presented): The process of claim 136, wherein the label is an isotope or a fluorophore.

Claim 138 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase insert into a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence if present in the sample and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 139 (previously presented): The process of claim 138, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 140 (previously presented): The process of claim 138, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 141 (previously presented): The process of claim 138, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

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Claim 142 (previously presented): The process of claim 141, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 143 (previously presented): The process of claim 142, wherein the label is an isotope or a fluorophore.

Claim 144 (previously presented): The process of claim 141, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 145 (previously presented): The process of claim 144, wherein the label is an isotope or a fluorophore.

Claim 146 (currently amended): An amplification reaction mixture for the quantitation of a target viral RNA sequence in a biological sample, said reaction mixture comprising:

a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase insert into a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.

Claim 147 (previously presented). The amplification reaction mixture of claim 146, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 148 (currently amended). A reverse transcription reaction mixture for reverse transcribing a target viral RNA sequence suspected of being present in a biological sample, said reaction mixture comprising:

a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase insert into a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified for initiating cDNA synthesis to provide a target viral cDNA and a reference sequence cDNA, whereby following reverse transcription the resulting target viral and reference sequence cDNAs can serve as templates for amplification for providing amplified reference RNA sequence and amplified target viral RNA sequence.

Claim 149 (previously presented). The reverse transcription reaction mixture of claim 148, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 150 (currently amended): A kit for the quantitation of a target viral RNA sequence in a biological sample comprising individual containers which provide:

a known quantity of a reference RNA sequence, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase insert into a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.

Claim 151 (previously presented). The kit of claim 150, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 152 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

(i) selecting a sequence present in the target viral RNA;

(ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence consists of the selected target viral RNA sequence with a multibase deletion from a site within the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;

(iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;

(iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and

(v) determining the amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

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Claim 153 (previously presented): The process of claim 152, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 154 (previously presented): The process of claim 152, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 155 (previously presented): The process of claim 152, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 156 (previously presented): The process of claim 155, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 157 (previously presented): The process of claim 156, wherein the label is an isotope or a fluorophore.

Claim 158 (previously presented): The process of claim 155, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 159 (previously presented): The process of claim 158, wherein the label is an isotope or a fluorophore.

Claim 160 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;

(ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence consists of the selected target viral RNA sequence with a multibase deletion from a site within the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;

(iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;

(iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and

(v) determining the amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 161 (previously presented): The process of claim 160, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 162 (previously presented): The process of claim 160, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 163 (previously presented): The process of claim 160, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 164 (previously presented): The process of claim 163, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 165 (previously presented): The process of claim 164, wherein the label is an isotope or a fluorophore.

Claim 166 (previously presented): The process of claim 163, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 167 (previously presented): The process of claim 166, wherein the label is an isotope or a fluorophore.

Claim 168 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase deletion from a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 169 (previously presented): The process of claim 168, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 170 (previously presented): The process of claim 168, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 171 (previously presented): The process of claim 168, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 172 (previously presented): The process of claim 171, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 173 (previously presented): The process of claim 172, wherein the label is an isotope or a fluorophore.

Claim 174 (previously presented): The process of claim 171, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 175 (previously presented): The process of claim 174, wherein the label is an isotope or a fluorophore.

Claim 176 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase deletion from a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence if present in the sample and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 177 (previously presented): The process of claim 176, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 178 (previously presented): The process of claim 176, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 179 (previously presented): The process of claim 176, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

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Claim 180 (previously presented): The process of claim 179, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 181 (previously presented): The process of claim 180, wherein the label is an isotope or a fluorophore.

Claim 182 (previously presented): The process of claim 179, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 183 (previously presented): The process of claim 182, wherein the label is an isotope or a fluorophore.

Claim 184 (currently amended): An amplification reaction mixture for the quantitation of a target viral RNA sequence in a biological sample, said reaction mixture comprising:

a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase deletion from a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.

Claim 185 (previously presented): The amplification reaction mixture of claim 184, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 186 (currently amended). A reverse transcription reaction mixture for reverse transcribing a target viral RNA sequence suspected of being present in a biological sample, said reaction mixture comprising:

a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase deletion from a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified for initiating cDNA synthesis to provide a target viral cDNA and a reference sequence cDNA, whereby following reverse transcription the resulting target viral and reference sequence cDNAs can serve as templates for amplification for providing amplified reference RNA sequence and amplified target viral RNA sequence.

Claim 187 (previously presented): The reverse transcription reaction mixture of claim 186, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 188 (currently amended): A kit for the quantitation of a target viral RNA sequence in a biological sample comprising individual containers which provide:

a known quantity of a reference RNA sequence, wherein the reference RNA sequence consists of the target viral RNA sequence with a multibase deletion from a site within the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.

Claim 189 (previously presented): The kit of claim 188, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 190 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

(i) selecting a sequence present in the target viral RNA;

(ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;

(iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;

(iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and

(v) determining the amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 191 (previously presented): The process of claim 190, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the selected target viral RNA

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sequence, a sequence not present in the selected target viral RNA sequence and a sequence present in the selected target viral RNA sequence.

Claim 192 (previously presented): The process of claim 190, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 193 (previously presented): The process of claim 190, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 194 (previously presented): The process of claim 190, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 195 (previously presented): The process of claim 194, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 196 (previously presented): The process of claim 195, wherein the label is an isotope or a fluorophore.

Claim 197 (previously presented): The process of claim 194, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 198 (previously presented): The process of claim 197, wherein the label is an isotope or a fluorophore.

Claim 199 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;
- (ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;
- (iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;
- (iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and
- (v) determining the amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 200 (previously presented): The process of claim 199, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the selected target viral RNA sequence, a sequence not present in the selected target viral RNA sequence and a sequence present in the selected target viral RNA sequence.

Claim 201 (previously presented): The process of claim 199, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

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Claim 202 (previously presented): The process of claim 199, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 203 (previously presented): The process of claim 199, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 204 (previously presented): The process of claim 203, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 205 (previously presented): The process of claim 204, wherein the label is an isotope or a fluorophore.

Claim 206 (previously presented): The process of claim 203, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 207 (previously presented): The process of claim 206, wherein the label is an isotope or a fluorophore.

Claim 208 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 209 (previously presented): The process of claim 208, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the target viral RNA sequence, a sequence not present in the target viral RNA sequence and a sequence present in the target viral RNA sequence.

Claim 210 (previously presented): The process of claim 208, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 211 (previously presented): The process of claim 208, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 212 (previously presented): The process of claim 208, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 213 (previously presented): The process of claim 212, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 214 (previously presented): The process of claim 213, wherein the label is an isotope or a fluorophore.

Claim 215 (previously presented): The process of claim 212, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 216 (previously presented): The process of claim 215, wherein the label is an isotope or a fluorophore.

Claim 217 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence if present in the sample and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

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Claim 218 (previously presented): The process of claim 217, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the target viral RNA sequence, a sequence not present in the target viral RNA sequence and a sequence present in the target viral RNA sequence.

Claim 219 (previously presented): The process of claim 217, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 220 (previously presented): The process of claim 217, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 221 (previously presented): The process of claim 217, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 222 (previously presented): The process of claim 221, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 223 (previously presented): The process of claim 222, wherein the label is an isotope or a fluorophore.

Claim 224 (previously presented): The process of claim 221, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 225 (previously presented): The process of claim 224, wherein the label is an isotope or a fluorophore.

Claim 226 (currently amended): An amplification reaction mixture for the quantitation of a target viral RNA sequence in a biological sample, said reaction mixture comprising:

a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.

Claim 227 (previously presented): The amplification reaction mixture of claim 226, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the target viral RNA sequence, a sequence not present in the target viral RNA sequence and a sequence present in the target viral RNA sequence.

Claim 228 (previously presented): The amplification reaction mixture of claim 226, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 229 (currently amended). A reverse transcription reaction mixture for reverse transcribing a target viral RNA sequence suspected of being present in a biological sample, said reaction mixture comprising:

a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA

sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified for initiating cDNA synthesis to provide a target viral cDNA and a reference sequence cDNA, whereby following reverse transcription the resulting target viral and reference sequence cDNAs can serve as templates for amplification for providing amplified reference RNA sequence and amplified target viral RNA sequence.

Claim 230 (previously presented): The reverse transcription reaction mixture of claim 229, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the target viral RNA sequence, a sequence not present in the target viral RNA sequence and a sequence present in the target viral RNA sequence.

Claim 231 (previously presented). The reverse transcription reaction mixture of claim 229, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 232 (currently amended): A kit for the quantitation of a target viral RNA sequence in a biological sample comprising individual containers which provide:

a known quantity of a reference RNA sequence, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence are of similar length and are capable of being amplified by the same oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.

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Claim 233 (previously presented): The kit of claim 232, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the target viral RNA sequence, a sequence not present in the target viral RNA sequence and a sequence present in the target viral RNA sequence.

Claim 234 (previously presented): The kit of claim 232, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.